9. (New) Process according to claim 6, wherein said polymer layer comprises polyacrylonitrile having a melting point of about 175°C and said first heated sealing surface has a temperature of about 200°C.

10. (New) Process according to claim 9, wherein said second heated sealing surface has a temperature of about 200°C.

11. (New) Device for performing the process according to Claim 6, comprising a sealing unit with heated sealing tools and a transport device for the pack material, wherein the sealing unit comprises at least one sealing head having, in succession in the direction of advance, two or more identical contact area structures corresponding to the predetermined weld lines for transmitting temperature and pressure to the pack material, with the length of one contact area structure in the direction of advance corresponding to the advancement cycle.

12. (New) Device according to claim 11 wherein the sealing unit comprises a first and a second cooperating, heated sealing head the second sealing head being arranged or configured on the side of the pack material facing away from the first sealing head

REMARKS

The Examiner is respectfully requested to reconsider the claims of this application, as amended above in response to the Office Action mailed August 1, 2002, and the following remarks, with the formal drawings submitted on November 1, 2002. The amended claims are believed to be definite and to distinguish applicants' invention over the cited prior art. However, we believe that a brief summary of applicants' invention and the advantages it provides will facilitate a discussion of the issues raised in the Office Action.

The invention described and claimed in this application provides processes and equipment for producing hot seal packs, such as those used for transdermal therapeutic systems. As in prior art processes, applicants seal two webs or laps having at least one layer of a heat sealable or weldable polymer such as high-density polyethylene, polyacrylonitrile or SURLYN®. Since this is a production process, it is desirable to produce the sealed packages as rapidly as possible. Thus, it is desirable to use sealing tools with a temperature considerably above the melting point of the polymer to quickly complete the seal. However, the high temperatures and high pressures involved in many conventional processes can cause blistering of the weldable polymer or other degradation. Applicants' process and equipment make it possible to produce sound welds and packages with sealing tool temperatures lower

than those customarily employed and with equal or even shorter cycle times, i.e., the time required to produce one heat-sealed package. This is accomplished by performing the heat-sealing operation in two steps, at adjacent heat-sealing stations, as defined in the amended and new claims submitted herewith, with the twin webs or laps of packaging material being advanced sequentially or incrementally from one heat-sealing station to the next. The sealing operation for any given package in the web begins at a first sealing station and is completed at a second sealing station. While the sealing operation is being completed, for a first package, at the second heating station, another package is receiving the initial step in the heat-sealing operation at the first heating station. The total sealing time for any individual package can be doubled or multiplied by an even higher factor without increasing the cycle time or production rate. Seals can be completed with lower sealing temperatures and/or with shorter cycle times than in conventional processes.

Claim Rejections – 35 U.S.C. §112

The amended and new claims of this application now describe applicants' process and equipment in terms of the incremental, sequential sealing steps that enable them to use lower sealing tool temperatures, increased sealing periods and/or reduced cycle times. Two of the phrases quoted and objected to in the Office Action: "the temperature of the tool is set at a lower temperature" and "increasing the sealing period by a factor" have been deleted. The third - "only slightly above the melting point" – has been deleted from amended claims 1 and 4, and changed to "slightly above the melting point <u>of said polymer</u>" in new claims 6 and 11. We submit that those skilled in the art will understand what is intended, and that this term in definite.

Relative terms have been rejected as indefinite in some situations, but

> "words such as 'substantially,' 'relatively,' 'and 'closely' . . . do not render a claim fatally indefinite if the specification provides a standard for measuring substantiality, relativity or closeness such that one skilled in the art can determine whether a particular product or process falls within the language of the claim." <u>*3 Chisum on Patents,*</u> § 8.03(c) at p 8-62 (Matthew Bender & Co., Inc.).

In a leading case on this issue, *Georgia-Pacific v. United States Plywood Corp,* 258 F.2d 124, 118 USPQ 122 (2d Cir. 1958), the court had to consider claims for:

> "[A] plywood panel having a face ply [with] grooves of random depth over the surfaces, . . . such grooves . . . being *sufficiently closely spaced* to localize . . . the normal stresses arising from shrinking, expanding and the like, and to prevent accumulation of such stresses across any appreciable width of

the ply, and also to largely destroy the normal grained effect." (118 USPQ at 130-31, emphasis added) The court held that:

> "We think that the essence of the invention and the reasons why it cannot be more precisely described reasonably appears from the above paragraphs which are a portion of the specification. The patent covers a striated plywood surface formed by gouging our 'a multitude of closely spaced grooves.' . . . The number of grooves, their size and configuration, the size of the ribs, and the depth of the grooving are variable within limits, and the infinite permutation of variables preclude a definite statement of limitations." (118 USPQ at 133)

The *Georgia*-Pacific court based their decision on a number of prior cases, including the landmark decision in *Eibel Co. v Minnesota & Ontario Paper Co*, 261 U.S. 45 (1923), and *Musher Foundation v. Alba Trading Co*, 150 F.2d 885, 66 USPQ 183 (2 Cir. 1945), which held, in an opinion by Judge Learned Hand, that a claim for a "method of treating a glyceride oil [comprising] infusing said oil at *slightly elevated temperature* with a *small amount* of a *low moisture* containing, dehydrated macerated oil for a *short period* . . ." (66 USPQ 185, emphasis added) was definite.

In *Eibel* the United States Supreme Court held that the words "substantial" and "high" were not indefinite because they were necessitated by variations in the practice of the patent and because those skilled in the art, with the disclosure of the patent and their knowledge of the prior art could understand the scope of the patent.

These decisions have been followed repeatedly by diverse courts, including the Court of Appeals for the Federal Circuit and the Court of Appeals for the District of Columbia, which held, in *Charvat v. Commissioner of Patents*, 182 USPQ 577 (1974), that "slightly" spread apart was not overly ambiguous when read with applicant's specification (182 USPQ at 587).

With the guidance provided by these decisions, we need to examine the disclosure of this application. It lists well-known weldable polymers, such as high density polyethylene, polyacrylonitrile and SURYLN® that are suitable for use in this invention. Melting temperatures for these and other suitable polymers are well known. Applicants provide guidance as to heating tool temperatures in this specification, and in new claims 7-10, listing specific temperatures preferred for high density polyethylene and BAREX® acrylonitrile. Optimal polymer temperatures and heating tool temperatures will vary, depending on diverse factors such as the specific weldable polymer employed, the heat transfer characteristics of other materials in the packaging laminate, and the lengths of the heating and indexing steps in the welding cycle. But those skilled in the art will understand from prior experience, or will

be able to determine without undue experimentation, the temperatures and heating times that specific polymers and packaging laminates can endure without blistering or other degradation. Thus, we submit that the amended claims of this application meet the standards established by decisions such as those cited above. The term "slightly above the melting point of the polymer" is not indefinite.

Claims 2 and 5, which were rejected, respectively, on the grounds that it was unclear if pressure was lowered during the cycle or set at a lower level relative to the reference prior art pressure; and that it was unclear what was intended by the phase "factor is two," have been deleted. With these amendments, all claims are believed to particularly point out and distinctly claim the subject matter which applicants regard as their invention. Withdrawal of the rejections under 35 U.S.C. §112 is respectfully requested.

Claim Rejections – 35 U.S.C. §103

Claim 1 was rejected under 35 U.S.C. 103(a) as being unpatentable over admitted prior art in view of U.S. 3,830,681 to Wilson. The Office Action alleged that forming strong seals without distortion, as disclosed by Wilson, would have been obvious to one skilled in the art. The present invention and the process disclosed by Wilson both address the same issues, namely providing an improved quality of welded seams by preventing blistering due to evaporation of moisture in the welding zone. However, they attack this problem in substantially different ways.

Wilson teaches a method and apparatus for heat sealing individual plastic bags already filled with the desired product. Thus, the heat sealing process has to be carried out while the bag is handing in a vertical position. He uses an impulse sealer to provide localized heating and achieve welding temperatures in a focused zone without overheating surrounding areas. This may avoid the blistering problem. But with Wilson's system, the longer clamping times referred to in the Office Action would inevitably increase the cycle times, and decrease the output.

In Wilson's process a contaminant particle **132** between the walls of the pouch **130** is extruded upon gripping pressure by the force caused by the particularly formed resilient anvil **122** fixed to the sealing jaw **74**. The anvil touches the pouch initially in its horizontal plane bisecting the anvil and then the anvil is deformed due to further pressure and extrudes the contaminant (Figures 6-8). As a result, the walls of the pouch are firmly forced together along each other and are subsequently sealed by a heat impulse, generated by a flat nichrome

resistance heating ribbon **94** which is placed at the gripping jaw. During the entire sealing process, the sealing head moves along with the pouch (col. 6, lines, 39-40).

In contrast to Wilson's process and equipment, the process and equipment of the present invention, as defined by the new and amended claims of this application, use two heated sealing heads, arranged on opposite sides of the continuous pack material, with multiple contact surfaces whose length and position correspond to the advancement cycle for the pack material. The sealing heads remain stationary. They do not move with the material being sealed, as do Wilson's. Furthermore, the present invention does not seal filled pouches. Two laps of continuous pack material are used. one placed on top of the other, and the transdermal therapeutic systems are placed between the two laps. Then all four sides of the resulting package are sealed simultaneously by the action of the cooperating heated sealing heads. The laps and the sheet-like transdermal therapeutic systems are set horizontally. Rather than extruding any moisture between the laps, as suggested by Wilson, the formation of blisters is prevented in the present process by one or more subsequent sealing steps. The laps are advanced stepwise between the individual sealing periods. Heat and pressure is applied to the same predetermined lines during the subsequent sealing step or steps, thus providing sound welds without lengthened individual sealing steps or elevated sealing tool temperatures. The subsequent sealing step or steps, which are not disclosed or suggested by Wilson, provide sound welds with reduced heat and pressure, as compared to sealing the laps in a single step. The process disclosed by Wilson requires a relatively high clamping pressure (col.. 9, lines 64-66) This is in contrast to the process of the present invention, which reduces the pressure exerted by the sealing tool (p 2, 2nd paragraph).

In applicants' process and equipment, as defined in the amended and new claims of this application, quality welds are produce with longer sealing times and lower temperatures by using multiple sealing steps at multiple sealing stations and advancing the web of packages from sealing station to sealing station. Since the sealing times are longer, the sealing temperatures can be lower. At the same time, equivalent or shorter cycle times or production rates can be achieved. Wilson does not disclose or suggest applicant's combination of temperatures slightly above the melting point of the polymer being sealed, and sequential sealing stations. Thus, claim 1 is believed to be in allowable over Wilson, and such action is respectfully requested.

Since claims 2 and 5 have been cancelled, the rejections of these claims based on Wilson and U.S. 5,131,213 to Shanklin et al or U.S. 5,204,181 to Suzuki et al are moot, and extended discussion seems unwarranted. We will note, however, that neither Shanklin et al

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Klaus Schumann, Frank Seibertz and Peter Steinborn
Serial No.	:	09/763,267
Filed	:	April 16, 2001
Title	:	METHOD FOR PRODUCING HEAT BONDED PACKAGES AND TOOL FOR IMPLEMENTING SAID METHOD
Examiner	:	Sing P Chan
Art Unit	:	1734
Attorney's Docket	:	RO0234US (#90568)

ATTACHMENT TO AMENDMENT
MARKED CLAIMS

The following set of marked claims, with additions underlined and deletions ~~struck out,~~ is attached to the Amendment submitted herewith pursuant to 37 CFR § 1.121(c)(1)(ii).

1. (Twice Amended) Process for producing hot-seal packs for transdermal therapeutic systems, by transporting, in a predetermined cycle through a sealing unit, two laps, a first lap and a second lap, of continuous pack material composed of two or more layers the first lap having a weldable polymer layer lying against the second lap, and the second lap having a weldable polymer layer lying against the first lap, and, using a sealing tool which acts upon both laps, in order to produce a weld along predetermined lines, bringing the laps into contact with pressure and with a temperature of above the melting point of the polymer, for a sealing period, which process comprises:

~~increasing, while the cycle remains the same, the sealing period by a factor, and~~

~~the temperature of the heated sealing heads of the sealing tool being lowered in response to said increase of the sealing period, to reduce the temperature reached within the pack material to a temperature only slightly above the melting point of the polymer layer.~~

bringing first area of said two laps into contact along predetermined lines, with pressure and at a temperature above the melting point of the weldable polymer, with a sealing

unit comprising a first heated sealing head and a second heated sealing head, the second sealing head being arranged or configured on a side of the pack material facing away from said first sealing head, and said sealing heads having, in succession in a direction of advance, first and second contact area structures corresponding to the predetermined weld lines, with the length of one contact area structure in a direction of advance corresponding to an advancement cycle;

advancing the pack material; and

applying pressure and heat to said first area of said laps with said second contact area of said sealing head, and simultaneously bringing second areas of said laps into contact along predetermined lines, with pressure and at a temperature above the melting point of the weldable polymer, with said first contact area of said sealing head.

4. (Amended) Device for performing the process according to Claim 1, comprising ~~a sealing unit with heated sealing tools and~~ a transport device for the pack material and a ~~, wherein the~~ sealing unit ~~comprises~~ comprising a first heated sealing head and a second cooperating, heated sealing head, the second sealing head being arranged or configured on the side of the pack material facing away from the first sealing head, and said sealing heads having, in succession in the direction of advance, two or more identical contact area structures corresponding to the predetermined weld lines for transmitting temperature and pressure to the pack material, with the length of one contact area structure in the direction of advance corresponding to the advancement cycle.

or Suzuki et al add anything to Wilson with respect to a critical feature of applicants' process, device and claims - the combination of multiple sealing steps and stations, and lower temperatures. Shanklin teaches a particular sealing jaw which is characterized in that the jaws are provided with a reciprocal knife, located between the jaws and operating against an elastomeric bed that has a longitudinal slot to receive the knife during the sealing/cutting operation. Such an operation is not possible if all four sides of the resulting pouch are to be sealed simultaneously. Furthermore, Shanklin discloses that the sealing saws clamp the film tightly against the corners of the slot in the elastomeric bed. (col. 2, lines 39-42). Hence, considerable pressure has to be exerted on the welding line, which is avoided by the present invention. Shanklin does not suggest reducing the pressure exerted by the sealing tool to avoid evaporation of moisture between the laps. Shanklin does not suggest the use of two heated sealing heads which cooperate and have contact surfaces whose length and spacing correspond to the advancement cycle. Thus, we submit that the claims of this application are not disclosed or suggested by any reasonable combination of Wilson and Shanklin.

Claim 1 includes material that is similar to cancelled claim 3, which was rejected as unpatentable over Wilson in view of U.S. 3,813,846 to Doering, Jr. Thus, claim 1 will be treated as having been rejected as unpatentable over Wilson and Doering, Jr. We, submit, however, that the amended claims of this application are not obvious in view of these disclosures. Their processes are designed for vastly different applications, and features of one process or system would not be suitable for the other. Moreover, it is not apparent, absent applicants' disclosure, how one skilled in the art might modify either Wilson's moving impulse sealing head or Doering's butter pat packager to arrive at applicants' process and equipment. The amended claims of this application define processes and equipment for hot sealing packs for transdermal therapeutic pouches, a far more demanding application than the one facing Doering, who discloses a process and system for sealing thermoplastic film to relatively rigid butter pat trays.

As noted above, Wilson uses an impulse sealer to provide localized heating. In Doering's process, heat is applied from one side only, because only the upper die member is heated (col. 3, last paragraph). The lower matching part of the sealing tool is not uniform, but consists of transverse bars **68** and vertically movable longitudinal bars **69**. This system would be difficult to heat, and Doering does not use or appear to contemplate two sided heating, or use of disclose lowered heating tool temperatures. Doering applies high pressure, e.g. one ton per tray or one ton per square inch (column 5, lines 11-14), for an extremely short sealing time (ibid: . . . "a fraction of a second") and, presumably, although temperatures

are not discussed, relatively high temperatures. The objective is to "facilitate complete sealing in an exceptionally short period of time." (column 4, lines 42-43). This requires adjustments that would not be suitable for heat sealing facing laps of heat sealable polymer to form packages for critical material or items such as transdermal therapeutic packages. For example, the lower part of Doering's sealing unit consists of a series of individual transverse bars **68** and vertically movable longitudinal bars **69**, on a lower die member **66**, that support the formed and filled tray of butter pats, while criss-crossed sealing projections **65** on an upper die member **64** heat seal the covering sheet **52** to the filled tray (column 3, line 64 to column 4, line 33). Heating the complex lower die member, with the transverse bars and movable longitudinal bars, would be a daunting task, and apparently only the upper projections **65** are heated. (column 4, lines 27-29: ". . . the projections heat seal the engaged portions of the sheet **52** to the engaged portions of sheet **49**.") This is definitely a disadvantage, compared with applicants' process and equipment, as defined in claims 6 and 11, wherein heat is applied from both sides of the mating laps. Doering must use higher temperatures and, even with higher temperatures, will have difficulty achieving relatively uniform temperatures. This is exacerbated by his extremely short contact periods. This process does not appear suitable for sealing two webs or laps of weldable thermoplastic film with the process and apparatus defined by the amended claims herein. In view of the different applications for Wilson and Doering's processes and equipment, and the differences in their approaches and equipment, we submit that one skilled in the art would be unlikely to combine the teachings of these radically different systems. Furthermore, there is nothing in either reference that would point one toward the processes and equipment defined by the revised claims herein.. Thus, we submit that amended claim 1, new claim 6 and the other claims of this application, which depend from claim 1 or claim 6, are in condition for allowance.

Claim 4, which depends from claim 1, should be allowable with the base claim. However, a few words about the rejection of claim 4 as being unpatentable over admitted prior art in view of Doering and optionally Wilson may be in order. As noted in the Office Action, Doering discloses a heated sealing head with repeated sealing elements in the direction of advance for repeat sealing operation, which improves throughput. (Col. 4, lines 20-35) However, as noted above, Doering does not use, disclose or suggest temperatures slightly above the welding point of the polymers being welded. He uses very high pressures and extremely short heating cycles, which require high sealing tool temperatures. It is unlikely that anyone skilled in the art would try to combine the vastly different processes and

systems of Doering and Wilson. And there is nothing in either reference, or in any reasonable combination of the references, that discloses or suggests the specific combination of heating steps and elements defined by the amended claims of this application, or the advantages that applicants provide with these specific combinations of steps and elements.

CONCLUSION

In view of the foregoing amendments and remarks, we submit that: 1) the amended claims of this application particularly point out and define what applicants regard as their invention, thus satisfying the requirements of 35 USC § 112; and 2) the processes and equipment defined by these claims are not obvious in view of the cited prior art, either alone or in combination. Allowance of the amended claims remaining in this application is believed to be in order, and is respectfully requested.

Respectfully submitted,

Date: December 2, 2002

By: _____

D. Peter Hochberg, Reg. No. 24,603

DPH/jr

Att.: Marked Claims; Petition and Fee for Extension of Time

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MAIL CERTIFICATION UNDER 37 CFR 1.8??

I hereby certify that this paper (along with any paper referred to as being attached hereto or transmitted herewith) is being deposited with the United States Postal Service as first class mail in an envelope addressed: Box Response - Fee, Commissioner for Patents, Washington, D.C. 20231.

Date: December 2, 2002

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James A. Rich